K063032

COMFORT
COMFORT ORTHOPEDIC CO., LTD.
www.comfort.com.tw
No.120,Nan Shiang Tsuen,Shoei Shang Shiang,Chia-yi,Taiwan,R.O.C.608
TEL : 886-5-2892093
FAX : 886-5-2890070

OCT 16 2006

" 510(k) SUMMARY "

Submitter's Name: ***COMFORT ORTHOPEDIC CO., LTD.***
N0. 120, NAN SHIANG TSUEN, SHOEI SHANG SHIANG, CHIA-YI, TAIWAN, ROC

Date summary prepared: September 29, 2006

Device Name:

Proprietary Name:	COMFORT SCOOTER, LY-EW415
Common or Usual Name:	Electric Scooter
Classification Name:	Motorized 3-Wheeled Vehicle, Class II, 21 CFR 890.3800

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a seated position.

Description of the device:

The COMFORT SCOOTER, LY-EW415 is an indoor / outdoor Electric Scooter that is battery operated. It has a base with four-wheeled with a seat. The movement of the Wheelchair is controlled by the rider who uses hand controls located at the top of the steering column. The device can be disassembled for transport and is provided with an onboard battery charger.

Performance Testing:

EMC Report ANSI / RESNA WC/Vol.2-1998, CISPR 11: 1990, EN61000-3-2: 1995, IEC61000-3-3: 1995 (Electrically Powered Wheelchairs, controller, and their chargers – requirements and test methods)

Legally marketed device for substantial equivalence comparison:

COMFORT WINDJOY SCOOTER LY-EW302 (K022369)

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C.1 SUMMARY TABLE

ITEMS	SUBJECT DEVICE	PREDICATE DEVICE 1
BRAND NAME	*COMFORT*	*COMFORT*
MANUFACTURER	COMFORT	COMFORT
SERIES	FUTURE	WINDJOY
MODEL NO	LY-EW415	LY-EW302
510K NO	TBA	K022369
INTENDED USE	SAME	*The device is intended for medical purposes to provide mobility to persons restricted to a seated position.*
Overall dimension		
Overall length	59.8" / 152 cm	48"
Overall width	28.3" / 72 cm	24.4"
Max loading	180 kgs / 400 lbs	265 lbs
Electronics	SAME	Dynamic Rhino series
Batteries		
Quantity	Two	Two
Type	Sealed lead acid, 75Ah 12VDC	Sealed lead acid, 40Ah 12VDC
Range per charge	75 km / 46.8 miles	28 miles

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ITEMS	SUBJECT DEVICE	PREDICATE DEVICE 1
Front tires	4.00-5 (pneumatic)	85 x 260 mm
Rear tires	3.00-10 (pneumatic)	4.10 / 3.50-5"
Maximum speed	8 km / 5.0 mph	5.5 mph
Turning radius	180 cm / 70.8"	43.3"
Back upholstery	SAME	Fabric
Scooter weight	140 kgs / 308 lbs (with battery)	165 lbs (w/o battery)
RECHARGER	DC 24V 8A Remote	DC 24V 5A Remote
Safe climbing angle	SAME	12^0
Warranty		
3 years	SAME	Main frame
1 year		Controller / gear motor main components w/o exhaustive and wear par

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C.2 COMPARISON SUMMARY

(We place the related information for the predicate device in the following pages.)

The overall dimensions and visional appearance are similar, and the dimensions for the new device are larger than that of the predicate device. The device of the smaller dimensions can be fitted into most of the ordinary car trunk. Our new device may not be fitted into small car trunk, but this is NOT related to the safe aspect. Besides, a device of larger dimensions can hold more mass and possess more balance. It certainly has more safety during moving and turning.

The **batteries** used are same supplier and they are certificated by UL. The **control** systems for the two devices are same supplier; it is Dynamic Rhino series controller types for the two devices. The **recharge** for the two devices are also used the same resource and they are certified by UL. Besides, the **back upholstery** is the same material, and also passed the resistance ignition test by SGS. The safety and performance functions of two systems are assured and validated. They are substantially equivalent.

The maximum speed is 0.5 mph difference for the two devices. The throttle tiller can continuously adjust the speeds. The operators can set the adequate speed according to their feeling and need, i.e., outdoor or indoor, and the maximum speed differences do not mean any performance differences. The new device has lower maximum speed, thus leading to more safety and less hazard. They are substantially equivalent.

The battery chargers types are almost the same; only for the output electric current is 8A for the new device and 5A for the predicate device. The current differences lead to the charging period differences or arise from the different battery capacity, not related with safety aspect.

Based on the above the information and the analysis, we know that the subject device and the predicate device have the same intended use, the same technological aspects and only minor differences exist. We believe that FDA can decide the subject device and the predicate device are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2006

Comfort Orthopedic Co., Ltd.
% Dr. Jen Ke-Min
ROC Chinese-European Industrial Research Society
No. 58, Fu-Chiun Street
Hsin-Chu City,
China (Taiwan) 30067

Re: K063032
Trade/Device Name: Comfort Scooter, LY-EW415
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: Class II
Product Code: INI
Dated: September 29, 2006
Received: October 3, 2006

Dear Dr. Ke-Min:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (K) Number (If Known): K

Device Name: *COMFORT SCOOTER, LY-EW415*

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted t a sitting position.

Prescription Use _____ AND/OR Over-The-Counter Use √

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative, and Neurological Devices

510(k) Number K063038